UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,664	01/22/2004	David J. Beebe	282.033	5152

23598 7590 06/29/2007

BOYLE FREDRICKSON NEWHOLM STEIN & GRATZ, S.C.
250 E. WISCONSIN AVENUE
SUITE 1030
MILWAUKEE, WI 53202

EXAMINER	
GILBERT, ANDREW M	

ART UNIT	PAPER NUMBER
3767	

NOTIFICATION DATE	DELIVERY MODE
06/29/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@boylefred.com

Office Action Summary	Application No.	Applicant(s)	
	10/762,664	BEEBE ET AL.	
	Examiner	Art Unit	
	Andrew M. Gilbert	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18 and 20-25* is/are pending in the application.

4a) Of the above claim(s) *9,17,20 and 25* is/are withdrawn from consideration.

5)☒ Claim(s) *21-24* is/are allowed.

6)☒ Claim(s) *1-8,10-16 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 September 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/23/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/23/2007 has been entered.

Acknowledgments

2. This office action is in response to the reply filed on 2/23/2007.

3. In the reply, the Applicant amended claims 1,10, 18 and 21. Claims 9, 17, 20, and 25 remain withdrawn.

Specification

4. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification fails to adequately provide proper antecedent basis for "a predetermined fluid" (clm 1 & 10). The Examiner is unclear as to what the "a predetermined fluid" is: Is it the hydrogel (50)? Is it the buffer solution injected to the hydrogel (50)? Is it the physiological fluid of the patient interacting with the hydrogel trigger (42)? The Examiner suggests explicitly reciting what the predetermined fluid is in the specification or modifying the claims. The Examiner has

interpreted the claim limitation to be the physiological fluid of the patient that interacts with the hydrogel (42). Appropriate correction is required.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 1, 7, 10, 15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims recite and claim a patient's physiological fluids. This is improper because claiming part of human body is not eligible subject matter. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-8, 10-16, 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Independent claims 1, 10 recite the limitation that the pressure source is directly responsive to a predetermined fluid. The Examiner is unclear on the metes and bounds of this claim limitation in regards to the Applicant's invention. It appears that the pressure source is filled with an expandable hydrogel that expands and exerts pressure on the fluid reservoir upon injection of a buffer solution into the pressure source. However, it appears that the pressure source is limited in expansion by the fact that the reservoir is blocked by a hydrogel trigger which responds

by expanding or retracting to exposure to a predetermined physical property of the patient. Thus, when the hydrogel trigger retracts the reservoir fluid outlet opens and fluid flows out of the collapsible reservoir under pressure from a now expanding pressure source. It appears that the pressure source cannot expand from a 1st to 2nd configuration purely by exposure to the buffer solution, but rather requires the retraction of the hydrogel trigger to open the fluid outlet to urge fluid from the reservoir. Thus, the pressure source cannot be said to be expandable in direct response to exposure to a predetermined fluid because act of expansion is dependent and, as it appears, limitated by the hydrogel trigger of the reservoir outlet. For purposes of Examination, the Examiner has interpreted the claim limitation as being that the pressure source is indirectly responsive to a predetermined fluid to adjust between a first and second configuration. Appropriate correction is required.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1-6, 10-15 are rejected under 35 U.S.C. 102(b) as being anticipated by van Lintel, hereafter "Lintel" (5224843). Lintel discloses a microfluidic device (Fig 1) for delivering a drug to an individual, the individual having physiological fluids therein, comprising: a reservoir (15); an output needle (10; col 3, lns 37-38) having an input in communication with the reservoir and an output receivable within the individual; and a pressure source (13) engageable with the reservoir and having an adjustable configuration directly responsive to a predetermined fluid between a first configuration and a second configuration (col 3, lns 45-50); further comprising a flexible membrane (12) isolating the pressure source from the reservoir; further comprising a valve (18) operatively connecting the input of the output needle and the reservoir (Fig 1-2; wherein the valve defines a chamber (18d) having an input (col 4, lns 38-40) communicating with the reservoir and an output (col 4, lns 38-43) communicating with the input of the output needle; wherein the valve includes a flexible membrane (18a) and a trigger (18c) disposed in the trigger receiving portion (Fig 1) in the chamber of the valve and having a first configuration (col 4, lns 26-50) preventing the flow of the drug through the chamber and a second configuration (col 4, lns 26-50) allowing the flow of the drug through the chamber; wherein the pressure source is isolated from the physiological fluids of the individual (Fig 1-2), further comprising a first sensing needle (10; col 3, lns 37-38) having an input receivable in the individual and an output (3) within the trigger receiving portion of the chamber (Fig 1), the first sensing needle being capable of allowing physiological fluids to pass from the individual to the trigger receiving portion of the chamber; wherein the output needle is removable from the body (10; col 3, lns 37-38).

11. Claims 1, 2, 10-12, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Eckenhoff et al (4552561). Eckenhoff et al discloses a microfluidic device (Fig 8) for delivering a drug to an individual, the individual having physiological fluids therein, comprising: a reservoir (25); an output needle (22) having an input in communication with the reservoir and an output receivable within the individual; and a pressure source (18) engageable with the reservoir and having an adjustable configuration directly responsive to a predetermined fluid between a first configuration and a second configuration; wherein the pressure source is isolated from the physiological fluids of the individual (Fig 8), further comprising a flexible membrane (10) isolating the pressure source from the reservoir; wherein the output needle is removable from the body (Fig 2, 8); further including an adhesive (6) for fixing the body to the individual; and a pressure source including a hydrogel member (18) expandable in response to exposure to a predetermined physical property (col 4, lns 29-35; col 5, lns 12-col 6, lns 28) and engageable with the reservoir to urge the drug from the reservoir through the output needle as the hydrogel member expands (col 4, lns 29-35; col 5, lns 12-col 6, lns 28; Figs 8, 13).

12. Claims 1-3, 10-12 are rejected under 35 U.S.C. 102(e) as being anticipated by Couvillon, Jr. et al (2004/0068224). Couvillon, Jr. et al discloses a microfluidic device (Fig 3) for delivering a drug to an individual, the individual having physiological fluids therein, comprising: a reservoir (124); an output needle (120; [0051]) having an input in communication with the reservoir and an output receivable within the individual; and a pressure source (112, 114) engageable with the reservoir and having an adjustable

configuration directly responsive to a predetermined fluid between a first configuration and a second configuration (Fig 3, 7, [0080]; wherein the Examiner notes that the Applicant's claim limitations allow for a device with a sensor sensing a predetermined fluid or a characteristic of a predetermined fluid and then relaying the results to controller and then to a pressure source to actuate the pressure source from a first to second configuration); wherein the pressure source is isolated from the physiological fluids of the individual (Fig 3,7), further comprising a flexible membrane (117) isolating the pressure source from the reservoir; a valve operable connecting the input of the output needle and the reservoir (158); wherein the output needle is removable from the body ([0051]); and a pressure source including a hydrogel member (112) expandable in response to exposure to a predetermined physical property ([0031-0038; 0044]; wherein the Examiner notes that an electrical current is a predetermined physical property) and engageable with the reserviour to urge the drug from the reservoir through the output needle as the hydrogel member expands (Fig 3).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lintel. Lintel discloses the invention substantially as claimed except for expressly disclosing a second sensing needle having an input receivable in the individual and an output within

the trigger receiving portion of the chamber, the second sensing needle allowing physiological fluids to pass from the individual to the trigger receiving portion of the chamber. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have a second sensing needle having an input receivable in the individual and an output within the trigger receiving portion of the chamber, the second sensing needle allowing physiological fluids to pass from the individual to the trigger receiving portion of the chamber because the Applicant has not disclosed that having a second sensing needle provides an advantage, is used for a particular purpose, or solves a stated problem. Furthermore, one of ordinary skill in the art would have expected the Applicants invention to perform equally well with the single sensing needle of Lintel because it has been held that mere duplication of essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8. Therefore, it would have been an obvious matter of design choice to modify Lintel to obtain the invention as specified in claim 7.

15. Claims 8 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lintel in view of Beebe et al (6523559). Lintel discloses the invention substantially as claimed except for wherein the trigger includes a hydrogel post, the hydrogel post expandable in response to exposure to a predetermined condition. Beebe et al teaches that it is known to have wherein the trigger includes a hydrogel post (56), the hydrogel post expandable in response to exposure to a predetermined condition (col 5, lns 29-67) for the purpose of having a self-regulating microfluidic device responsive to changes in value of a solution to regulate the feedback to compensate and return the value of the

solution to the desired level without the need for any external power sources and/or electronics. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the trigger as taught by Lintel with the hydrogel post as taught by Beebe et al for the purpose of having a self-regulating microfluidic device responsive to changes in value of a solution to regulate the feedback to compensate and return the value of the solution to the desired level without the need for any external power sources and/or electronics.

16. Claims 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Couvillon, Jr. et al in view of Connelly et al (6689100). Couvillon, Jr. et al discloses the invention substantially as claimed (see above discussion) except for an adhesive for affixing the body to the individual. Connelley et al teaches that it is known to have an adhesive (38) for affixing the body to the individual for the purpose of preventing leakage and ensuring efficiency of the delivery (col 4, lns 34-36). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Couvillon, Jr. et al with the adhesive as taught by Connelly et al for the purpose of preventing leakage and ensuring efficiency of the delivery (col 4, lns 34-36).

Allowable Subject Matter

17. Claims 21-24 are allowed.

Response to Arguments

18. Applicant's arguments with respect to claims 1-8, 10-16, 18 have been considered but are moot in view of the new ground(s) of rejection.

19. The Applicant argues that van Lintel doses not disclose that the pressure source directly responds to a predetermined fluid (remarks, pg 9, paragraph 2). The remarks are not persuasive because the limitation "directly responsive to a predetermined fluid" wherein the predetermined fluid is a physiological fluid of the patient (see examiner's interpretation as discussed above) acts to directly activate a sensor (col 3, lns 42-50) that through a controller actuates the pressure source from a 1st to 2nd configuration. This response occurs directly in response to the physiological fluid of the patient. The Examiner suggests adding structural limitations detailing the structure and action of the physiological fluid of the patient acting on the hydrogel trigger that opens the fluid outlet to allow fluid to be urged out of the reservoir into the patient by the pressure source as it expands.

20. The Applicant argues that Couvillion, Jr. et al does not disclose the pressure source directly responding to the predetermined fluid (Remarks, pg 10, paragraph 2). The remarks are not persuasive because the limitation "directly responsive to a predetermined fluid" wherein the predetermined fluid is a physiological fluid of the patient (see examiner's interpretation as discussed above) acts to directly activate a sensor that through a controller actuates the pressure source from a 1st to 2nd configuration. This response occurs directly in response to the physiological fluid of the patient.

21. The Examiner further recommends strongly and explicitly defining the metes and bounds of the predetermined fluid, predetermined determined condition, predetermined physical property.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Andrew Gilbert

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER